



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,458	01/07/2002	Jeffrey Andrew Borenstein		6837

7590 01/08/2007
Jeffrey Borenstein, M.D.
80 East End Avenue
New York, NY 10028

EXAMINER

COBANOGU, DILEK B

ART UNIT	PAPER NUMBER
----------	--------------

3626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/038,458

Applicant(s)

BORENSTEIN ET AL.

Examiner

Dilek B. Cobanoglu

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 06/12/2006. Claim 1 has been cancelled. Newly added claims 2-14 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 2-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 2 discloses a method for monitoring compliance of a patient with a medication regimen and the method steps include: logging on to a web site, registering a patient at the web site, receiving a report at the web site from the patient indicating whether the patient has taken medication and receiving a report at the web site from the patient indicating whether the patient has any symptoms after taking the medication. There is only one logging on to the web site in the first two steps, and then the third step is receiving a report from the patient. The omitted steps are:

monitoring compliance. It is not clear if there is any active monitoring within the claimed method.

B. Claim 6 discloses the method as recited in claim 2, further comprising:

accessing the web site, reviewing any information reported by the patient; and making a clinical intervention. It's not clear how the clinical intervention is done, is it done by a software program with statistical information or is it a physician's commentary decision.

C. Claim 14 discloses both a system or an apparatus which has components and a method comprising steps such as reporting. Since it is unclear as to whether Applicant seeks protection for a method or an apparatus, claim 14 is rejected under 35 U.S.C. 112, second paragraph for being indefinite for failing to particularly point out and distinctly claim the subject matter.

D. Claims 3-5, 7-13 are also rejected under 35 U.S.C. 112, second paragraph because of the dependency.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 2 is rejected under 35 U.S.C. 101 because the claimed invention does not produce a tangible result. A claim is directed to a practical application when there is either a physical transformation or when a useful, concrete and tangible result is produced. The claimed invention recites a method of monitoring compliance of a patient

with medication regimen, the method comprising: logging on to a web site; registering a patient at a web site; receiving a report at the web site from the patient indicating whether the patient has taken medication and receiving a report at the web site from the patient indicating whether the patient has any symptoms after taking the medication.

There is no tangible result obtained at the end of the claimed invention; receiving a report from the patient indicating whether the patient has any symptoms after taking the medication is not a tangible result, this result may be an indicator, signal, or comment of the patient.

6. Claim 14 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. MPEP section 2105 states that

"If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter. Furthermore, the claimed invention must be examined with regard to all issues pertinent to patentability, and any applicable rejections under 35 U.S.C. 102, 103, or 112 must also be made."

Claim 14 discloses a system enabling the monitoring of compliance of a patient with a medication regimen, the system comprising: a network, a case manager connected to the network through a first browser, the case manager effective to perform the steps of logging onto a web site, and registering a patient at the web site, the patient connected to the network through a second browser, the patient effective to perform the steps of logging onto the web site, reporting whether the patient has taken medication, and reporting whether the patient has any

symptoms after taking the medication. The claimed case manager and also patient are human beings and therefore the claimed invention is directed to nonstatutory subject matter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Surwit et al. (hereinafter Surwit) (U.S. Patent No. 6,980,958 B1) in view of Bianco et al. (hereinafter Bianco) (U.S. Patent Publication NO. 2002/00828/65 A1).

A. As per claim 2, Surwit discloses a method for monitoring compliance of a patient with a medication regimen and the method steps include:

- i. receiving a report at the web site from the patient indicating whether the patient has taken medication and receiving a report at the web site from the patient indicating whether the patient has any symptoms after taking the medication (Surwit; col. 4, lines 47-67, col. 5, lines 5-10, 13-15 and col. 8, lines 6-19).

Surwit fails to expressly teach the logging on to a web site and registering a patient at the web site, per se, since it appears that Surwit is more directed to accessing to a system for monitoring,

diagnosing, and treating medical conditions of remotely located patients using logon security. However, this feature is well known in the art, as evidenced by Bianco.

In particular, Bianco discloses a logging on to a web site and registering a patient at the web site (Bianco; paragraphs 0097, 0102-0104).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Bianco with the motivation of patient having access to various features and functionalities and also access to secure communication with physicians. (Bianco; par. 0140)

B. As per claim 3, Surwit discloses the method as recited in claim 2,

Surwit fails to expressly teach the patient enters his/her own code, per se, since it appears that Surwit is more directed to accessing to a system for monitoring, diagnosing, and treating medical conditions of remotely located patients using logon security (Surwit; col. 13, lines 14-35). However, this feature is well known in the art, as evidenced by Bianco.

In particular, Bianco discloses a patient enters his/her own code (Bianco; paragraphs 0104).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as

disclosed by Bianco with the motivation of patient obtaining a personalized web page. (Bianco; par. 0106)

C. As per claim 4, Surwit discloses the method as recited in claim 2, wherein a case manager performs the logging (Surwit; col. 13, lines 14-35).

D. As per claim 5, Surwit discloses the method as recited in claim 2, further comprising receiving a report at the web site from the patient describing any side effects (Surwit; col. 4, lines 47-67, col. 5, lines 1-10 and col. 11, lines 1-27).

The obviousness of modifying the teaching of Surwit to include a web site (as taught by Bianco) is as addressed above in the rejection of claim 2 and 3 and incorporated herein.

E. As per claim 6, Surwit discloses the method as recited in claim 2, further comprising: reviewing any information reported by the patient and making a clinical intervention (Surwit; col. 5, lines 48-52).

The obviousness of modifying the teaching of Surwit to include accessing a web site (as taught by Bianco) is as addressed above in the rejection of claim 2 and 3 and incorporated herein.

F. As per claim 7, Surwit discloses the method as recited in claim 6, wherein the clinical intervention is based on a stage of treatment (Surwit; col. 5, lines 48-52).

G. As per claim 8, Surwit discloses the method as recited in claim 6, wherein the reviewing and making is performed by a physician (Surwit; col. 5, lines 48-52).

H. As per claim 9, Surwit discloses the method as recited in claim 8, wherein communication between the physician and the patient is asynchronous (Surwit; col. 5, lines 48-52).

I. As per claim 10, Surwit discloses the method as recited in claim 8 (Surwit; col. 5, lines 48-52), wherein the physician enters his/her own code at the web site

Surwit fails to expressly teach the physician enters his/her own code, per se, since it appears that Surwit is more directed to accessing to a system for monitoring, diagnosing, and treating medical conditions of remotely located patients using logon security (Surwit; col. 13, lines 14-35).

However, this feature is well known in the art, as evidenced by Bianco.

In particular, Bianco discloses a physician enters his/her own code (Bianco; paragraphs 0097).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Bianco with the motivation of physicians to find out more information regarding the services of the healthcare information provider. (Bianco; par. 0097).

J. As per claim 11, Surwit discloses the method as recited in claim 6, wherein a case manager performs the reviewing and making (Surwit; col. 5, lines 48-57 and col. 20, lines 42-56).

K. As per claim 12, Surwit discloses the method as recited in claim 2, wherein the reports are received from the patient daily (Surwit; col. 13, line 64 to col. 14, line 35).

L. Claim 13 repeats the same limitations as claim 1, therefore is rejected with the same reasons explained above in the rejection of claim 1, and incorporated hereinwith.

M. Claim 14 repeats the same limitations as claim 1, therefore is rejected with the same reasons explained above in the rejection of claim 1, and incorporated hereinwith.

Response to Arguments

9. Applicant's arguments with respect to newly added claims 2-14 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3626

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dilek B. Cobanoglu whose telephone number is 571-272-8295. The examiner can normally be reached on 8-4:30.

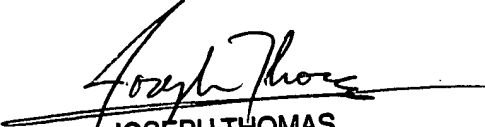
14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3626

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DBC

DBC
Art Unit 3626
01/04/2007


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER